

**A. Status of the Claims**

Per the Examiner's request, Applicants herein affirm the previous election and acknowledge claims 1-26 and 64 are currently pending. Applicants herein cancel claims 27-63 without prejudice and without acquiescence, although they reserve the right to pursue these claims in subsequent prosecution.

Claim 9 was objected to for a typographical error regarding dependency of the claim. Applicants herein correct this unintentional error.

New claims 65 and 66 are added herein. Support for claim 65 is on Page 31, L15-26, Page 33, L14-16, Page 35, L25-26, and on Page 38, L8-10. Support for claim 66 is in Figure 1.

The issues outstanding in this application are as follows:

- Claims 1, 2, 4, 10, 14, 17, 20, 21, 23, 26, and 64 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ersek *et al.* (U.S. Patent No. 5,258,028) ("Ersek").
- Claims 1-4, 10, 17, 20-23, 26, and 64 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Sheppard *et al.* (WO 94/08912) ("Sheppard").
- Claims 5, 6, 9, 11-13, and 22 are rejected under 35 U.S.C. §103 as allegedly being unpatentable over Ersek in view of Chen *et al.* (U.S. Patent No. 6,180,606) ("Chen").
- Claims 15 and 16 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ersek in view of Kondo *et al.* (JP 171546) ("Kondo").
- Claims 7, 8, 18, 19, and 24 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ersek in view of Kelly *et al.* (U.S. Patent No. 5,676,745) ("Kelly").
- Claim 25 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ersek.

**B. Issues under 35 U.S.C. §102(b)****1. Ersek**

Claims 1, 2, 4, 10, 14, 17, 20, 21, 23, 26, and 64 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ersek. Applicants respectfully assert that Claim 1 and the cited dependent claims are not anticipated by this reference.

Claim 1 of the pending application addresses the particle as being “shaped for use in an array of particles interlocked with one another” and that the extremities of an adjacent particle “facilitate interlocking of adjacent particles in an array.” The Examiner alleges that Ersek discloses an array of particles having an adequate porosity to allow ingrowth (col. 5, lines 49-56). Applicants respectfully disagree and herein set forth the language of Ersek cited by the Examiner:

The irregularities, pores and interstices are designed to have widths ranging from those having a diameter or opening size which will just accommodate the infiltration of a typical connective tissue fibril or protein molecule at the lower end to those large enough to accommodate ingrowth of much larger cross-linked protein, possible collagen protein, fibrillar structures or actual fibroblasts at the high end.

This text, in the section of the specification entitled “DESCRIPTION OF THE PREFERRED EMBODIMENT,” refers to the preferred embodiment set forth in Figs. 1 and 2. This text and the preceding text in the section refers to the surface irregularities illustrated in the preferred embodiment in Figs. 1 and 2. Applicants assert that the illustration of Fig. 5 shows no “irregularities” but, in fact, demonstrates well-defined extremities on the particle. Applicants further assert that the particles of the present invention definitely do not comprise surface irregularities.

More importantly, the Examiner contends that this text describes an array of particles, but Applicants find no teaching for the particles in an array. The text describes the irregularities, pores and interstices as having widths for accommodating infiltration of a fibril large enough to allow ingrowth (see the pores 11 in Figs. 1 and 2). The text does not state that the particles are present in an array and furthermore does not state that the particles are interlocked with one another, as Claim 1 of the present invention describes.

Furthermore, referring to Fig. 5, Applicants note that the differences in arm shape and size do not facilitate interlocking in an array, as set forth in Claim 1 of the present invention. That is, for example, in Fig. 5 the large arm pointing in a northwesterly direction would not fit for interlocking in the interstice of, for example, the two small arms facing northwesterly and northeasterly on the trio of arms in the forefront of the particle illustration.

A claim is anticipated only if each and every element as set forth in the claims is found in the reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, Applicants assert that Ersek does not anticipate Claim 1 and its dependent claims because it does not teach the elements of “said particle is shaped for use in an array of particles” and “wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array.” Thus, Applicants respectfully request removal of this rejection.

## **2. Sheppard**

Claims 1-4, 10, 17, 20-23, 26, and 64 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Sheppard. Applicants respectfully assert that Sheppard does not anticipate the claimed invention.

Fig. 2 of Sheppard illustrates an embodiment of a single particle, and Figs. 5 and 6 illustrate an embodiment wherein the particles are arranged in an array. Applicants assert these particles do not comprise an extremity having a circular transverse cross-sectional configuration, as set forth in Claim 1 and its dependent claims. Indeed, on Page 10, the description for Fig. 2 cites “six four-sided arms,” which *quid pro quo* means the cross-section of the arms can not be circular. Thus, Applicants assert Sheppard does not anticipate the cited claims and respectfully request that this rejection be removed.

## **C. Issues under 35 U.S.C. §103**

### **1. Prima facie Case of Obviousness Must be Established**

Claims 5, 6, 9, 11-13, and 22 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ersek in view of Chen; claims 15 and 16 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ersek in view of Kondo; claims 7, 8, 18, 19, and 24 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ersek in view

of Kelly; and claim 25 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Ersek.

Applicants respectfully assert that the cited claims are not obvious in light of Ersek alone or in combination with these references. As Applicants state *supra*, Ersek alone or combined does not contain or suggest all of the elements of Claim 1, and thus its dependent claims. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In light of this criteria, Applicants assert that the Office has not established a *prima facie* case of obviousness to reject the claims under 35 U.S.C. § 103. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, (Fed. Cir. 1991). Therefore, all of the 35 U.S.C. § 103 rejections over Ersek are improper, and Applicants respectfully request that the rejection be removed.

## **2. Obvious to Try Standard is an Improper Ground for Rejection**

Applicants also submit that the multiple rejections under 35 U.S.C. §103(a) are each an application of an “obvious to try” standard in the field of shaped bone particles. The “obvious to try” standard has been held to constitute an improper ground for a 35 USC § 103 rejection. *In re O’Farrell*, 858, F.2d 894, 903 (Fed. Cir. 1988). An “obvious-to-try” situation exists when a general disclosure may pique an inventor’s curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result or indicate that the claimed result would be obtained if certain directions were pursued. *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990).

## **D. Conclusion**

Thus, Applicants assert that the presently pending claims are novel, given that Ersek and Sheppard do not teach all of the elements of claim 1, and are nonobvious, given that all of the claim limitations are neither taught nor suggested by Ersek alone or in combination with Chen, Kondo, or Kelly.

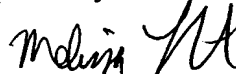
In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this

application to issue.

Applicants file herewith a Petition for Extension of Time and the requisite fee. Applicants believe that there are no other fees associated with the filing of this document. However, the Commissioner is hereby authorized to any other required fees associated with this filing, to Deposit Account No. 06-2375, under Order No. 10004751, from which the undersigned is authorized to draw.

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Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

9. (Amended Once) The particle of Claim [6] 4 wherein said particle is comprised of bioactive glass.

65. (New) The particle of Claim 1, wherein said particle is comprised of a resorbable material.

66. (New) The particle of Claim 1, wherein the angle between the axis of any two adjacent arms is ninety degrees.

**PENDING CLAIMS**

1. A shaped particle for use in treating a bone deficiency wherein said particle is shaped for use in an array of particles interlocked with one another, comprising:

a center portion; and

at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array.

2. The particle of Claim 1 wherein at least three of said extremities lie in a plane.

3. The particle of Claim 1 wherein said particle has six extremities.

4. The particle of Claim 1 wherein said particle is comprised of a material selected from the group consisting of ceramic, bioactive glass, polymer, polymer/ceramic composite, and polymer/glass composite.

5. The particle of Claim 4 wherein said ceramic is comprised of a calcium salt.

6. The particle of Claim 5 wherein said calcium salt is selected from the group consisting of calcium sulfate, calcium carbonate, calcium phosphate and calcium tartarate.

7. The particle of Claim 6 wherein said particle is comprised of calcium sulfate.

8. The particle of Claim 7 wherein said calcium sulfate is in the form of gypsum.

9. The particle of Claim 4 wherein said particle is comprised of bioactive glass.

10. The particle of Claim 4 wherein said particle is comprised of a polymer.

11. The particle of Claim 10 wherein said polymer is selected from the group consisting of polypropylene, polylactic acid, polyglycolic acid and polycaprolactone.

12. The particle of Claim 4 wherein said particle is comprised of a polymer/ceramic composite.

13. The particle of Claim 4 wherein said particle is comprised of a polymer/glass composite.

14. The particle of Claim 1 wherein said particle has a diameter of about 3-10 millimeters.

15. The particle of Claim 1 wherein said particle has a diameter of about 4-8 millimeters.

16. The particle of Claim 1 wherein said particle has a diameter of about 6 millimeters.

17. The array of Claim 1 wherein said array contains multiple particles.

18. The array of Claim 17 wherein said multiple particles are in a mixture of particles comprised of different materials.

19. The particles of Claim 18 wherein said different materials are selected from the group consisting of ceramic, calcium salt, bioactive glass, polymer, polymer/ceramic composite, and polymer/glass composite.

20. The particle of Claim 1 wherein said treatment of a bone deficiency is selected from the group consisting of augmentation of bone, repair of bone, replacement of bone, improvement of bone, strengthening of bone and healing of bone.

21. The bone deficiency of Claim 20 wherein said bone deficiency is selected from the group consisting of a fracture, break, loss of bone, weak bone, brittle bone, hole in bone, void in bone, disease of bone and degeneration of bone.



22. The disease of Claim 21 wherein said disease is selected from the group consisting of osteoporosis, Paget's disease, fibrous dysplasia, osteodystrophia, periodontal disease, osteopenia, osteopetrosis, primary hyperparathyroidism, hypophosphatasia, fibrous dysplasia, osteogenesis imperfecta, myeloma bone disease and bone malignancy.

23. The array of Claim 1 wherein said interlocking of said adjacent particles in said array provides adequate porosity to allow ingrowth from a host bone.

24. The array of Claim 23 wherein said porosity is between about 40% and about 80%.

25. The array of Claim 23 wherein said porosity is between about 60% and about 80%.

26. An array of shaped particles wherein said array comprises a plurality of shaped particles, said shaped particles comprising:

a center portion; and

at least four tapered extremities projecting from said center portion wherein said projections provide for interstitial spaces between adjacent extremities, each extremity having a base attached at said center portion, an opposite point, a length, and a circular transverse cross-sectional configuration, wherein said interstitial spaces of one said particle will accept at least one extremity of an adjacent said particle to facilitate interlocking of adjacent particles in said array of shaped particles, wherein said array of shaped particles provides for treating a bone deficiency.

64. The particle of Claim 1, wherein the particle is ceramic.

65. The particle of Claim 1, wherein said particle is comprised of a resorbable material.

66. The particle of Claim 1, wherein the angle between the axis of any two adjacent arms is ninety degrees.